

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Genomic Health Inc
301 Penobscot Dr
Redwood City
California
94063
USA

Holds Certificate No:

FM 669470

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacture, distribution and management of outsourced processes, for specimen collection kits, reagents and associated software required to support treatment decisions for invasive breast cancer.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-10-10

Latest Revision Date: 2022-03-17

Effective Date: 2021-10-10

Expiry Date: 2024-10-09



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